

**REMARKS**

Claims 120-139 are pending in the application. Claims 124, 129, 134 and 139 have been canceled. Accordingly, after the amendments presented herein have been entered, claims 120-123, 125-128, 130-133 and 135-138 will remain pending.

Cancellation of the claims should in no way be construed as an acquiescence to the merits of the Examiners rejections. *No new matter has been added.* Applicants reserve the right to pursue the claims as originally filed one or more separate applications.

***Claim Rejections – 35 U.S.C. §102***

Claim 129 has been rejected under 35 U.S.C. §102(b) as being anticipated by Christ *et al.*, U.S. 6,184,366 (hereinafter “Christ”). Without acquiescing to the merits of the rejection, and solely in the interest of expediting prosecution, Applicants have canceled claim 129. Applicants respectfully submit that the cancellation of claim 129 has rendered the above rejection under 35 U.S.C. §102(b) moot.

***Claim Rejections – 35 U.S.C. §103***

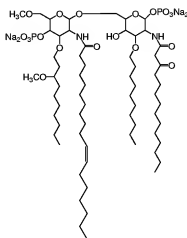
Claim 120-139 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Christ. Specifically, the Office Action states that it “would have been obvious to one of ordinary skill in the art to synthesize the compounds of the present application because the ‘366 patent discloses compounds with the same core structure as the instant application and discloses the use of the same protecting groups in the synthesis of compounds of similar structure.”

Applicants respectfully traverse the foregoing rejection, at least because Christ provides no motivation to make or use the compounds of the present invention. Applicants respectfully submit that, contrary to the Examiners assertion that “one of ordinary skill in the art would have reasonably expected compounds with similar structure... would have resulted in substantially similar or better properties,” it has been established that “...in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new

claimed compound.” (Takeda Chemical Industries, Ltd. v. Alphapharm PTY., Ltd. 83 U.S.P.Q.2D 1169 (Fed. Cir. 2007))

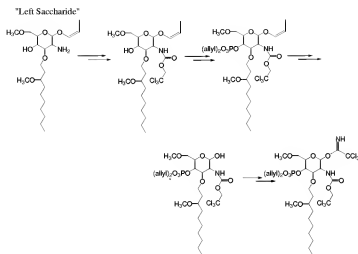
Applicants submit that Christ does not teach or suggest intermediates of the present invention, nor does Christ teach methods for making or using such intermediates. Moreover, Christ provides no reasonable expectation that any modification to intermediates provided therein could be accomplished, nor any reasonable expectation that intermediates having modifications would be successful in preparing the final product. Accordingly, the skilled artisan would have no reason to modify the known compounds of Christ in the particular manner described in the present invention.

The present invention is based, at least in part, on the discovery of an improved method for the production of a disaccharide compound, *e.g.*, :



The method can typically be broken down into three stages: the synthesis of the left saccharide, the synthesis of the right saccharide, and the coupling of the two saccharides.

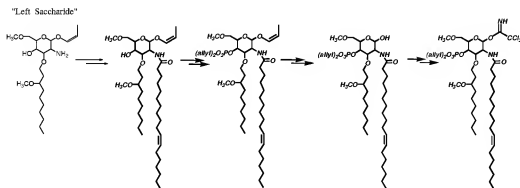
With regard to the left saccharide, and as shown in Scheme 1, Christ generally teaches the protection of the nitrogen group with Troc-Cl, followed by phosphorylation of the oxygen at carbon 5 of the ring, deprotection of the oxygen at carbon 2 of the ring and activation of the same oxygen.

**Scheme 1**

\*note in all schemes that double arrows are used to indicate any number of steps between intermediates.

Applicants respectfully point out that, in Christ, a reactive intermediate (e.g., Troc) is used to attach the alkanoyl group to the amine group.

In contrast, the present invention, as shown in Scheme 2, provides a method which effects the direct attachment of the long-chain alkanoyl group to the amine *without the need for a reactive (e.g., Troc) intermediate*.

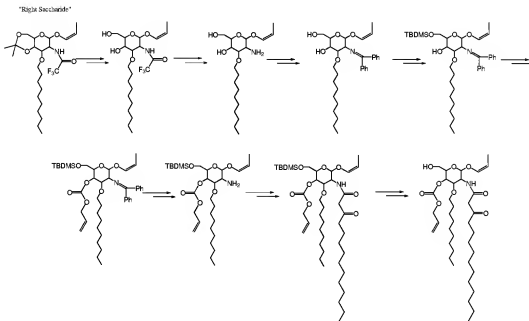
**Scheme 2**

Christ does not teach or suggest either the direct attachment of the long-chain alkanoyl group without the use of Troc protection *or* the addition of the long-chain alkanoyl group prior to the coupling of the left saccharide with the right saccharide. Moreover, Christ provides no reasonable expectation that direct attachment of the long-chain alkanoyl group without the use of Troc protection could be afforded. Accordingly, compounds which represent the uncoupled left

saccharide having a long chain alkanoyl group attached to the amine (*e.g.*, compounds bolded in Scheme 2) are novel and unobvious over Christ. Currently pending claims 120-123 and 130-133 reflect the intermediates that include such uncoupled, alkanoyl-containing compounds.

With regard to the right saccharide, and as shown in Scheme 3, Christ generally teaches production of a triflorocarbonate intermediate followed by removal of the cyclic acetal protecting group at positions 5 and 6 of the ring. A diphenylimine intermediate is then formed, followed by protection of the oxygens at carbon 5 and carbon 6 the ring. Christ then teaches removal of the diphenylimine (to form an amine), and subsequent reaction with a long-chain alkanoyl to form an alkanoyl amine.

**Scheme 3**



Applicants respectfully point out that, in Christ, the alkanoyl group was attached to the amine group after all of the hydroxy groups were properly protected. That is, because a carboxylic acid was used to modify the amine group, the hydroxy groups in Christ were (1) protected and (2) protected with a suitably acid-resistant group, *e.g.*, a group other than the cyclic acetal starting material. (It is well known that the addition of an acid to a cyclic acetal protecting group would remove the protecting group, leaving the two hydroxy groups open and susceptible to attack.)

In contrast, the present invention, as shown in Schemes 4 and 5, provides two methods for obtaining the right saccharide, which both effect the direct attachment of the long-chain



Christ does not teach or suggest the addition of the long-chain alkanoyl group without protecting the oxygens at positions 5 and 6 of the ring with suitably acid-resistant protecting groups. Moreover Christ provides no reasonable expectation that the long-chain alkanoyl group could be attached to the amine group of the saccharide without protecting both of the oxygens at positions 5 and 6 of the ring with suitably acid-resistant protecting groups. Accordingly, compounds having a fused-ring protecting group at position 5 and 6 on the ring (*e.g.*, compounds bolded in Scheme 5) are novel and unobvious over Christ. Currently pending claims 125-126 and 135-136 reflect such intermediates. Moreover, compounds having an unprotected oxygen group at position 5 or 6 on the ring (*e.g.*, compounds bolded in Scheme 4) are also novel and unobvious over Christ. Currently pending claims 127-128 and 137-138 reflect such intermediates.

Furthermore, Applicants respectfully submit that the intermediates of the present invention provide an advantage over Christ, at least because the methods for producing the disaccharide compounds which include such intermediates involve fewer steps and better overall final product yield.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a) and reconsideration of the claims.

**CONCLUSIONS**

In view of the foregoing, Applicant believes the pending application is in condition for allowance. The Examiner is invited to contact the undersigned with questions or comments with regard to this application.

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Respectfully submitted,

By /Elizabeth A. Hanley/  
Elizabeth A. Hanley, Esq.  
Registration No.: 33,505  
LAHIVE & COCKFIELD, LLP  
One Post Office Square  
Boston, Massachusetts 02109-2127  
(617) 227-7400  
(617) 742-4214 (Fax)  
Attorney/Agent For Applicant